

**What is claimed is:**

1. A biological fluid sampling and analyte concentration measurement device, said device comprising:
  - (a) at least one skin-piercing member comprising a biological fluid access opening;
  - (b) an electrochemical cell for measuring the concentration of analyte within the biological fluid, wherein the cell comprises at least one porous electrode; and
  - (c) a fluid transfer medium in fluid communication with the at least one piercing member and with the at least one porous electrode, wherein the fluid transfer medium transfers biological fluid present at the access opening of the at least one piercing member to the electrochemical cell.
2. The device of claim 1 wherein the fluid transfer medium comprises a hydrophilic porous material.
3. The device of claim 2 wherein the porous material comprises a distal portion associated with the piercing member and a proximal portion adjacent to the at least one porous electrode, wherein the proximal portion is more porous than the distal portion.
4. The device of claim 3 wherein the proximal portion is about 10 to 100 times more porous than the distal portion.
5. The device of claim 1 wherein the fluid transfer medium transfers biological fluid by means of a capillary force exerted on the biological fluid in its presence.
6. The device of claim 2 wherein the porous material is selected from the group consisting of polymers, ceramics, glass and silica.
7. The device of claim 1 wherein the electrochemical cell comprises two spaced-apart electrodes defining a reaction chamber and a selected reagent for chemically reacting with an analyte targeted for measurement.

8. The device of claim 7 wherein the distance between the electrodes is from about 10 to 300 microns.

9. The device of claim 8 wherein the distance between the electrodes is from about 10 to 150 microns.

10. The device according to claim 7 wherein the reagent is located on a surface of at least one electrode facing the reaction chamber.

11. The device of claim 7 wherein both electrodes are porous.

12. The device of claim 11 further comprising a housing having at least one vent hole for venting air from within the electrochemical cell.

13. The device of claim 1 wherein the biological fluid is interstitial fluid and the analyte is glucose.

14. The device of claim 2 further comprising a hydrophilic gel.

15. The device of claim 1 wherein the fluid transfer member comprises a plurality of pores.

16. The device of claim 15 wherein the pores exert a capillary force on biological fluid in contact with the pores.

17. The device of claim 15 wherein the pores have diameters in the range from about 0.1 to 50  $\mu\text{m}$ .

18. The device of claim 17 wherein the diameters are in the range from about 0.1 to 10  $\mu\text{m}$ .

19. A biological fluid sampling and analyte concentration measurement device, said device comprising:

- (a) an array of micro-needles, each micro-needle having an access opening;
- (b) a layer of porous material over the array;
- (c) a first layer of conductive material over the layer of porous material,

wherein the first layer of conductive material is porous and further wherein the access openings, the layer of porous material and the first layer of conductive material provide a fluid transfer pathway; and

(d) a second layer of conductive material, wherein the first layer of conductive material and the second layer of conductive material are spaced-apart, wherein biological fluid present at the access openings is caused to be transferred to the space between the first and second layers of conductive material.

20. The device of claim 19 further comprising a layer of insulating material over the second layer of conductive material.

21. The device of claim 19 wherein the array of micro-needles comprises an insulating material. /

22. The device of claim 19 further comprising a layer of reagent material between the first and second layers of conductive material wherein an analyte targeted for measurement present in the in the space between the first and second layers of conductive material chemically reacts with the reagent.

23. The device of claim 22 wherein the layer of reagent material contacts either the first layer of conductive material, the second layer of conductive material or both.

24. The device of claim 19 wherein the second layer of conductive material is porous.

25. The device of claim 24 further comprising an insulating layer over the second layer of porous conductive material, wherein the insulating layer has a venting hole therethrough.

26. The device of claim 19 wherein the biological fluid being sampled is interstitial fluid.

27. The device of claim 26 wherein the analyte is glucose and the reagent comprises a glucose oxidizing enzyme and a mediator.

28. The device of claim 27 wherein the enzyme is selected from a group consisting of glucose oxidase and glucose dehydrogenase.

29. The device of claim 28 wherein the mediator is ferricyanide.

30. The device of claim 19 wherein the micro-needles of the array of micro-needles have varying lengths.

31. An analyte sensor device, comprising:

- (a) an electrochemical cell comprising at least one porous electrode; and
- (b) a fluid transfer medium externally adjacent the at least one porous electrode.

32. The device of claim 31 wherein the fluid transfer medium comprises a more porous proximal portion and a less porous distal portion wherein the more porous proximal portion is adjacent the at least one porous electrode.

33. The device of claim 32 wherein the less porous distal portion comprises a distal surface having skin-piercing micro-protrusions formed thereon.

34. The device of claim 33 wherein the distal surface is non-porous region.

35. The device of claim 31 wherein the electrochemical cell comprises two porous electrodes.

36. A system for sampling biological fluid from the skin of a patient and measuring a target analyte within the biological fluid, the system comprising:

- (a) at least one device according to claim 1; and
- (b) a control means in electrical communication with the at least one device, the control means comprising:

(1) means for sending an electrical input signal to the device and for receiving an electrical output signal from the device, and

(2) a software algorithm which automatically calculates and determines the concentration of the target analyte in the biological sample upon receipt of the electrical output signal.

37. The system of claim 36 further comprising a display means in electrical communication with the control means for displaying information in the form of electrical signals received from the control means related to the sampling of the biological fluid and the measuring of the target analyte.

38. The system of claim 36 further comprising a housing wherein the control means is located within the housing and the device is mounted to the housing.

39. The system of claim 37 wherein the device is mounted to the housing by means of a lock-and-release mechanism.

40. The system of claim 38 further comprising user input buttons on the housing for providing user input to the control unit.

41. The system of claim 38 further comprising a display means on the housing for displaying information from the control means.

42. The system of claim 38 wherein the housing has a hand-held configuration.

43. A method for testing a biological fluid within the skin of a patient and for determining the concentration of a target analyte contained therein, the method comprising the steps of:

providing at least one micro-needle comprising an open distal end;  
inserting the at least one micro-needle into the skin to a selected depth;  
exerting a capillary force on the biological fluid present at the open distal end;

and

transferring the sampled biological fluid through a conductive material into a measurement chamber.

44. The method of claim 43 further comprising the steps of:

causing the sampled biological fluid to chemically react with a selected reagent within the measurement chamber;

providing a first signal to the measurement chamber; and

receiving a second signal from the measurement chamber, wherein the second electrical signal is representative of the concentration of the analyte in the sampled biological fluid.

45. The method according to claim 43 further comprising the steps of:

exerting a capillary force on the sampled biological fluid present in the measurement chamber; and

[0071] transferring the sampled biological fluid through a second conductive material.

46. The method according to claim 45 further comprising the step of venting air from the measurement chamber.

47. The method of 43 further comprising the step of deriving the concentration level of the analyte in the patient's blood from the second signal.

48. The method of claim 47 further comprising the step of displaying a numerical value representative of the concentration of the analyte in the patient's blood.

49. The method according to claim 48 wherein the step of deriving comprises using a software algorithm.

50. The method according to claim 43 wherein the biological fluid is interstitial fluid and the analyte is glucose.

51. A method for sampling a biological fluid within the skin of a patient and for measuring the concentration of one or more target analytes contained therein, the method comprising the steps of:

providing a biological fluid sampling and analyte measuring system according to claim 36 comprising a first sensor device operatively coupled to a control means;

operatively applying the sensor device to the patient's skin wherein the system samples the patient's biological fluid and measures the concentration of the one or more target analytes therein;

removing the sensor device from the patient's skin;

removing the first sensor device from the control means;

operatively coupling a second sensor device to the control means; and

repeating the above steps until the desired number of samplings and measurements have been performed.

52. A kit for sampling a biological fluid from the skin of a patient and for measuring the concentration of a analyte within the sampled biological fluid, the kit comprising:

at least one device according claim 1; and

a control means according to claim 36.

53. The kit of claim 52 wherein the at least one device is disposable and the control unit is reusable.

54. A kit for sampling a biological fluid from the skin of a patient and for measuring the concentration of a analyte within the sampled biological fluid, the kit comprising:  
a plurality of disposable devices according to claim 1.

55. The kit of claim 54 further comprising a support member wherein the plurality of micro-needles are arranged in an array on the support member.

56. A biological fluid sampling and analyte concentration measurement device, said device comprising:

- (a) at least one skin-piercing member comprising a biological fluid access opening;
- (b) a colorimetric measuring means for measuring the concentration of analyte within the biological fluid; and
- (c) a fluid transfer medium in fluid communication with the at least one piercing member and with the at least one porous electrode, wherein the fluid transfer medium transfers biological fluid present at the access opening of the at least one piercing member to the electrochemical cell.